Integrated Surface Electrical Stimulation Device for Therapeutic Applications

D. Howe[1,4], J. Dunning[2,4], S. L. Garverick[1,4], C. A. Zorman[1,4], K. Bogie[2,3,4]

1. Department of Electrical Engineering and Computer Science, Case Western Reserve University
2. Louis Stokes Cleveland Department of Veterans Affairs Medical Center
3. Department of Orthopaedics, Case Western Reserve University School of Medicine
4. Advanced Platform Technology Center, Louis Stokes Cleveland VA Medical Center

APT CENTER
TECHNICAL FOUNDATIONS FOR CLINICAL INNOVATIONS
A VA Research Center of Excellence

CASE WESTERN RESERVE UNIVERSITY
RESEARCH SHOWCASE CASE WESTERN RESERVE UNIVERSITY

Research Motivation:

Chronic ischemic wounds, including pressure ulcers, are a devastating secondary complication for many people with decreased mobility and compromised circulation.

Annual treatment costs have been estimated to be in excess of $1.3 billion per annum [1].

Electrical stimulation (ES) is one of only two therapeutic options to be recommended by the Agency for Health Care Policy and Research [2].

Acceptance has been limited due to both the technology used to deliver treatment and lack of standard treatment protocols.

Existing Treatment Methods

Electrical stimulation for the treatment of chronic wounds, most specifically pressure ulcers, was first reported nearly 40 years ago [7].

Critical evaluation of clinical efficacy indicates that although ES may be an effective treatment modality, there is currently no clear understanding of the basic mechanisms underlying the effects of ES in wound repair [4], [3].

Current clinical ES wound therapy uses surface stimulation devices, either battery or mains powered, i.e. tethered, and is provided only in the clinic setting

Treatment requires placing stimulating electrodes around the wound area at every treatment session and removing them post-treatment.

Frequent exposure of the wound area precludes maintenance of an optimally effective moist wound environment [5,6,7].

There may also be an increased infection risk due to repeated wound exposure.

Proposed Solution

The integrated surface stimulation device (ISSD) will provide the basis for a platform technology which is customizable for a diversity of short-term clinical applications. The initial design requirements are that the prototype device will contain all the components of a stimulation system within a lightweight portable device that;

- Is low-profile, flexible, disposable, safe *and* low-cost (less than $100)
- Provide an occlusive dressing, leading to an optimal moist wound healing microenvironment.
- Contains its own power supply, that can run continuously for up to 7days, i.e. is battery-powered.
- Provides single-channel, current-controlled electrical stimulation that is programmable for pre-defined range(s) of stimulation parameters, according to the specific application.
- Includes an intuitive user interface for selection and control of stimulation patterns.

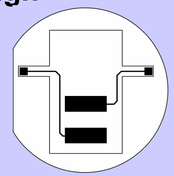
The ISSD will be a therapeutic electrical stimulation device that achieves high efficacy and safety *and* high acceptance by both clinicians and users.

Flexible Electrode Design

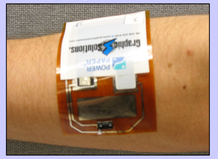
The ISSD is constructed on a flexible polyimide substrate with platinum stimulation electrodes. The substrate is processed on a 4” wafer platform using standard micro-fabrication patterning and etching techniques.

The electrodes and circuit board contacts are patterned on the bottom side of the polyimide, then the contacts are folded over to the top side. This technique eliminates the need for multilayer processing and via construction.

The ISSD substrate is then cut to size and mated with the printed circuit board using conductive epoxy.

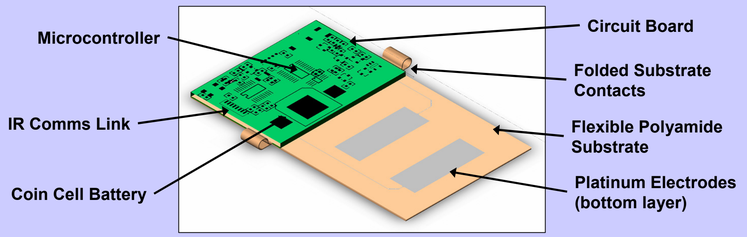


Substrate Layout on 4” wafer

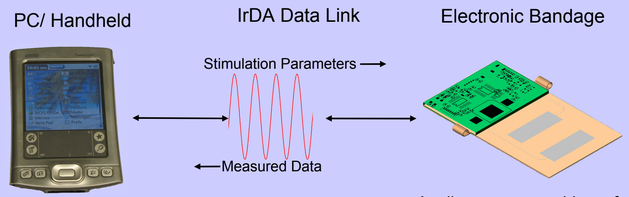


Prototype ISSD Mockup

ISSD Prototype CAD Model



ISSD System Design



- Generates stimulation parameters based on experimental design.
- Programs ISSD with stimulation parameters via infrared link.
- Retrieves and stores measured treatment data from bandage.

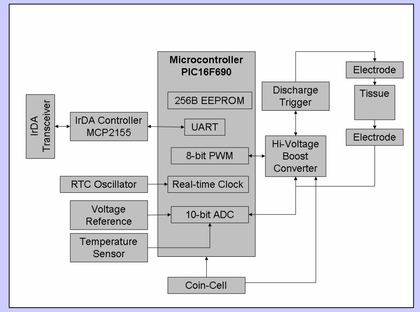
- Applies programmable surface stimulation to wound site for up to seven days.
- Measures and logs tissue temperature and resistance.
- Closed-loop control minimizes power consumption and identifies ISSD fault conditions.

ISSD Hardware Operation

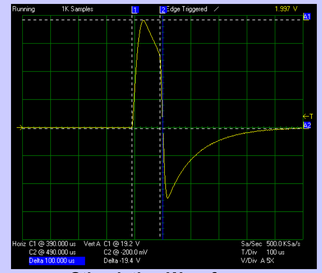
System controller:
ISSD hardware is centered around an 8-bit PIC microcontroller that controls all major device functions. The PIC integrates memory, communication, analog-to-digital conversion (ADC), and boost converter control functions into a 1cm^2 package.

Boost-mode voltage converter
Used to generate high voltages for wound stimulation from low voltage power supply. The microcontroller closely regulates stimulation voltage and shuts down the converter when idle.

Communication link
An IrDA transceiver and controller communicate with an external device. No specialized equipment is needed to use the ISSD.



ISSD Hardware Architecture



Stimulation Waveform

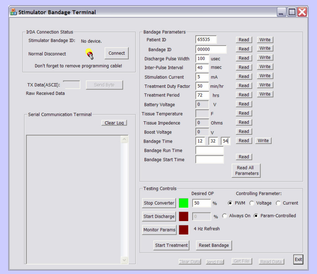
ISSD Software

Custom software interfaces with the ISSD and can be used on either a PC or handheld.

Functions:

- Programming stimulation parameters
- Downloading experimental data

Reduces programming effort and avoids costly mistakes. Downloaded data is readily exported to a statistical analysis software tool.



References

[1] Miller, H. and Delozier, J. Cost implications of the pressure ulcer treatment guideline. Columbia (MD), Center for Health Policy Studies. Contract No. 282-91-0070, 17, 1994

[2] Bergstrom N, Bennett MA, Carlson CE, et al. Treatment of Pressure Ulcers. Clinical Practice Guideline, No. 15. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 95-0652. December 1994

[3] Akai M, Kawashima N, Kimura T, Hayashi K. Electrical stimulation as an adjunct to spinal fusion: a meta-analysis of controlled clinical trials. Bioelectromagnetics. 2002; 23(7):496-504

[4] Field FK, Kerstein MD. Overview of wound healing in a moist environment. Am J Surg. 1994 Jan; 167(1A):2S-6S

[5] Cho CY, Lo JS. Dressing the part. Dermatol Clin. 1998 Jan; 16(1):25-47

[6] Metzger S. Clinical and financial advantages of moist wound management. Home Healthc Nurse. 2004 Sep; 22(9):586-90

[7] Assimacopoulos D. Wound healing promotion by the use of negative electric current. Am Surg. 1968 Jun; 34(6):423-31